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TITLE: Continuous Pre-hospital Data as a Predictor of Outcome Following Major Trauma: A Study Using Improved and Expanded Data

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14. ABSTRACT This study is designed to acquire near continuous physiologic measurements, beginning at the earliest practical time after injury, on large numbers of injured patients with severe trauma. The study will utilize commercially available FDA-certified monitoring equipment, operating in a fleet of ground EMS ambulances currently serving a large metropolitan area with multiple trauma centers. First Responders may represent the earliest opportunity to acquire meaningful medical data in injury cases. This data will be correlated with significant clinical outcomes within the first 24 hours of admission and entered into a research database. This is the second annual report for the subject project. During the reporting period, upgrade of five project ambulances was completed and pre-hospital patient data was acquired and processed for 29 cases. Analysis supports the hypothesis that ground EMS systems can provide earlier inception of data recording than helicopter services. A new physiological monitor device was deployed in an expanded fleet of ambulances and research to facilitate data collection and interpretation using the new device was initiated. Phase 2 of the subject project was initiated and planned work was re-directed based on results of early investigations. Work is underway to accelerate and expand data collection operations and to enhance data collection and analysis processes.

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Introduction

The reporting period for this report spans much of the activity described below including concluding work in Phase 1 of the subject project and initial work in Phase 2, and including two Statement of Work (SOW) modifications that were implemented as more information was gathered during preliminary research. This report describes activities and accomplishments beginning just after the Phase 1 field data collection operations (using an "old" physiological monitor device during March 2006) were being completed. The reporting period concludes with work occurring just after a modified SOW for Phase 2 was approved and preparations were underway for conduct of the first accelerated (manual) data collection interval (planned for April 2007) using a different "new" monitor.

The objective of this project is to develop, implement, and test a capability to collect relevant physiological and treatment data for seriously injured trauma patients in support of the U.S. Army's "Combat Critical Care Engineering" (CCCE) research task area. The information that is sought includes pre-hospital physiological data for qualifying patients as well as post-arrival and outcome data. This project represents one of the first attempts to accomplish these tasks in support of the CCCE program within a system of ground ambulances responding to incidents and caring for and transporting patients to Level 1 Trauma Centers. Ground Emergency Medical Services (EMS) represent the earliest practical opportunity, for most civilian traumatic injury cases, to begin to acquire needed patient data. This project builds upon the existing LifeLink mobile telemedicine project in San Antonio to accomplish these goals. The scope of the first phase of the subject project was to establish preliminary data collection capabilities in five San Antonio (SA) EMS ambulances operating within the LifeLink program and one receiving hospital to establish required research protocols and approvals to facilitate the data collection and research operations, to operate the data collection system for one month, and to examine the resulting data and draw preliminary conclusions about the capabilities of initiating pre-hospital data collection relatively early in qualifying trauma injury cases.

The work planned during Phase 1 of this project included development of the capability to extract and process data from the physiological monitor that was in use by the SA EMS system to acquire and monitor patient vital signs during patient treatment and transport. This was accomplished for the data-capable monitor that was available in a limited number of ground SA EMS ambulances operated by the participating ground EMS system. After the planned Phase 1 patient data collection interval was completed, however, Southwest Research Institute® (SwRI®) learned that a new and more capable physiological monitor was to be adopted by the SA EMS system. Based on this development, SwRI proposed an additional task (Task 4 of the modified SOW) for Phase 1 of the subject project at no additional cost in early June 2006. The proposed additional task facilitated work to research the new monitor and begin to develop a relevant proof-of-concept data extraction and process capability. The proposed no-cost SOW modification was formally approved later in the same month, and the planned completion date for Phase 1 was extended from June 22, 2006 to December 22, 2006 to accommodate the additional task.

SwRI provided a proposal to TATRC for Phase 2 of the subject project in November 2005. The scope of the proposed Phase 2 work was primarily aimed at refining the process and expanding the capacity for data collection as used during Phase 1 and to collect additional data. The proposed Phase 2 project was awarded in late July 2006.

Work began on Phase 2 of the subject project in early August 2006. The initial work in Phase 2 was focused on research aimed at improving the efficiency and sustainability (automation) of acquisition of needed pre-hospital patient physiological data. Two major components affecting this research and planning were (1) the data management capabilities of the monitor and (2) the logistical processes used within the SA EMS system relative to data collection. It was found that both of these "variables" were significantly affected by the introduction of the new monitor. The data collection and management capabilities of the new monitor were found to be limited and operator intensive. In addition, it was discovered that the data management capabilities of the new monitor and the data management processes and procedures practiced by the SA EMS system were evolving, with changes and improvements in both variables planned for the near future. Based on significant interaction with the SA EMS system and the manufacturer of the new monitor to better understand the current and evolving plans for the monitor capabilities and data management practices, SwRI submitted a request for a significant modification to the plans for Phase 2 work. This request was submitted in mid-December 2006 and formally approved in late February 2007.

The scope of work for the approved modified Phase 2 SOW re-directed planned project operations from further work to improve efficiency and automation of data collection processes built around the "old" LifePak 12 monitor as used in a limited number of SA EMS units. The introduction of the new monitor and the placement of new data-capable monitors in the entire fleet of ambulances in the SA EMS system provided opportunities for a greatly expanded volume of qualifying patient cases, resulting in a potentially much higher volume of data collection. Both the originally proposed and the modified Phase 2 SOW provided for early work to research, plan, and develop data capture and logistical technical and efficiency enhancements (automation) for physiological monitor operations and SA EMS data collection processes. The modified Phase 2 SOW added multiple data collection intervals of operations and included an accelerated initial data collection interval using the existing (but limited) new monitor configuration and SA EMS processes and procedures adapted to the features of the new monitor. Work was included in the modified Phase 2 plan to integrate further improvements in future project data collection and processing operations with evolving upgrades in capabilities and procedures planned for both the new monitor and the SA EMS system over the upcoming year. Additional data collection intervals planned for Phase 2 will be coordinated with milestones in the evolving monitor and SA EMS system data management upgrades.

Both the originally proposed and the modified SOW for Phase 2 also include additional elements of work in support of enhanced data mining and visualization and follow-on efforts in research of improved remote diagnostic ultrasound image transmission and interpretability.

Body

This section of the report presents discussion and significant accomplishments/problems encountered in the conduct of the subject project. The section is organized to present this information as associated with relevant tasks and subtasks of the approved SOWs for both phases of the project, including the added Task 4 modification of the SOW for Phase 1, early work in Phase 2, and work immediately following the approval of the proposed modification of the SOW for Phase 2 in February 2007. Efforts were made to focus early Phase 2 work on tasks that were consistent with the anticipated modification of the Phase 2 SOW (work common to both versions of the SOW) as reflected in the SOW Phase and Task headings in the later part of the body of the report.

PHASE 1 (initial award)

TASK 1 **To implement the EMS ambulance fleet for data collection and obtain Institutional Review Board (IRB) approvals for data collection protocols**.

Phase 1 (initial award)
Subtask 1.a Investigate monitor configuration and data collection process.

The pre-hospital data collection process for this project is required to be transparent to the patient care and transport mission of SA EMS as specified by the approved research protocol. This requirement guided the development of the process planned for the subject study, and SwRI worked closely with staff at SA EMS and the SA EMS Medical Director to accomplish this. A proof-of-concept (POC) process that was expected to yield usable data while meeting these requirements was established and used for the planned Phase 1 data collection interval of time, which was completed just prior to the beginning of the subject reporting period.

Phase 1 (initial award)
Subtask 1.b Implement data collection configuration in five ambulances.

The original SA EMS LifeLink ambulance fleet was being retired and replaced with new vehicles due to age and wear. SwRI accomplished the task of coordinating access to the relevant vehicles with SA EMS in order to remove the LifeLink equipment. The equipment recovery task was accomplished by SwRI and the Texas Department of Transportation (TxDOT) at a SA EMS facility. Five removed LifeLink equipment sets were refurbished, tested, and prepared for installation in replacement ambulances by SwRI.

Gaining access to an active ambulance for upgrade required that the subject ambulance be removed from active service and replaced with a backup vehicle including movement of active operational and patient care equipment to the backup ambulance. Installation of LifeLink equipment involved significant disassembly and technical preparation of each ambulance, including routing of cabling and installing antennas. This work was followed by re-assembly of the ambulance and test of the installed system. Once the upgrade was completed, the ambulance could be returned to SA EMS for re-configuration and acceptance for return-to-service. Snapshots of the project ambulances during typical LifeLink equipment installations are presented in Figures 1 through 4 for reference.

Figure 1. Ambulance in LifeLink Lab at SwRI during Upgrade

Figure 2. Work Inside Patient Cabin during Upgrade

Figure 3. In-Process LifeLink Equipment Install-Forward Bulkhead

Figure 4. In-Process LifeLink Equipment Install-Headseat Area

SwRI and SA EMS coordinated access to the five project ambulances, and installation, test of LifeLink equipment, and return-to-service for the five ambulances was accomplished during the reporting period. The unique SA EMS identification numbers for the five project ambulances and the dates of return-to-service are presented in Table 1.

Table 1. SA EMS Ambulance and Date of Return-to-Service after LifeLink Upgrade

SA EMS Vehicle Number	Date of Return-to-Service
#8481	4/6/2006
#8487	4/13/2006
#8480	4/28/2006
#8490	5/5/2006
#8479	5/12/06

New SA EMS ambulances were specified to contain special wiring and other accommodations built into the ambulances to accommodate installation and operation of LifeLink equipment. During the installation of refurbished LifeLink equipment, however, it was discovered that some of the pre-arranged wiring and accommodations were omitted or incorrectly installed at the factory. SwRI developed a work-around for these problems for currently available newer SA EMS ambulances and coordinated correction of the problems with SA EMS and the ambulance manufacturer for future vehicles.

Phase 1 (initial award)
Subtask 1.c Specify adaptations required for database.

This work was completed prior to the subject reporting period.

Phase 1 (initial award)
Subtask 1.d Develop and submit protocols for three IRB approvals (local, one hospital, and the Human Subjects Research Review Board [HSRRB]).

This work was completed prior to the subject reporting period.

Phase 1 (initial award)
Subtask 1.e Semi-Annual Report

Quarterly reports (or substituted participation in Programmatic Line Reviews) were submitted for the subject project. A semi-annual report was planned in the proposed SOW but would have been redundant and was not included in the reporting requirements for the subject project.

PHASE 1 (initial award)
TASK 2 To implement adaptations for the existing Trauma Vitals Database for San Antonio data and set up the data collection organization.

Phase 1 (initial award)
Subtask 2.a Implement data collection facilities at one hospital.

In preparation for the subject project pre-hospital and post-arrival data collection operations, SwRI met with staff from the US Army Institute of Surgical Research (USAISR) and Brooke Army Medical Center (BAMC) to discuss and coordinate the work. SwRI and USAISR collaborated to implement a modification to the existing Cooperative Research and Development Agreement (CRDA) between the two institutions to accommodate delivery by SwRI of planned financial support to USAISR for related Research Nurse data collection activities, and SwRI subsequently processed the planned Inter-Agency Transfer of these funds to USAISR.

Phase 1 (initial award)
Subtask 2.b Implement database adaptations.

This work was completed prior to the subject reporting period.

Phase 1 (initial award)
Subtask 2.c Implement the data collection system and familiarize EMS and hospital personnel with project procedures.

SwRI coordinated with research staff at USAISR to prepare for post-arrival data collection for the subject SA EMS qualifying cases and to arrive at a mutual understanding of information content and procedures.

SwRI also worked to acquire and extract case timing information from runsheets and case files as well as from collected monitor data to support the investigation of elapsed time intervals between estimated times of injury and the beginning of data collection for qualifying cases. USAISR was also able to access equivalent information for helicopter services operating within the San Antonio area. With this information, USAISR was able to conduct a statistical analysis of the elapsed times between injury and the start of data collection for the two types of services.

Phase 1
Subtask 2.d Annual Report

An annual report for Phase 1 was delivered on June 20, 2005. A second annual report (this report) addresses operations in both Phase 1 and Phase 2 and covers the reporting period of April 1, 2006 through March 31, 2007.

PHASE 1 (initial award)
TASK 3 To conduct operations to collect data.

Phase 1 (initial award)
Subtask 3.a Collect hospital and pre-hospital data derived from existing practices for Code 3 trauma patients transported to one hospital by SAFD LifeLink ambulances for one month.

This work was completed prior to the subject reporting period.

Phase 1 (initial award)
Subtask 3.b React to problems in facilities and organizations.

This work was completed prior to the subject reporting period.

Phase 1 (initial award)
Subtask 3.c Review and analyze data and refine procedures.

Qualifying code 3 trauma cases that were cared for during the pre-hospital interval by SA EMS during the data collection period were identified. Electronic files of pre-hospital physiological data for qualifying cases were recovered from the monitors in use during the case retrospectively. SA EMS run-sheets and case-file forms without personal identifying information but containing relevant case time and other diagnosis, care, and treatment data needed for the subject research and analysis program were also collected for qualifying cases.

The encrypted electronic pre-hospital data files were processed to yield data files that were readable and usable in the CCCE program. SA EMS unit identification and time information within the processed files facilitated association between the electronic files and the run-sheets for the qualifying cases. Identified cases that did not meet the requirements of the approved protocol (underage, etc.) or for which electronic data files were corrupted or suspect were excluded from the study.

The availability of large amounts of relevant patient pre-hospital data resulting from the just-completed data collection interval provided an opportunity to exercise the data processing capabilities developed earlier in Phase 1 and to examine and compare the resulting USAISR XML report-formatted data to reports produced by the monitor manufacturer case reporting system. SwRI worked to interactively exercise, examine, and validate the data process capability to ultimately address noted questionable results. This process resulted in high confidence in the accuracy of the XML data reports of collected patient pre-hospital data for the CCCE program.

Elapsed times between estimated times-of-injury and the onset of post-injury pre-hospital data collection were derived from data within the SA EMS records and the electronic data files.

The identified qualifying cases and associated data files and case time data were reviewed for accuracy by SwRI and SA EMS consultant staff. The qualifying case data was then reviewed by

the Medical Director for SA EMS, who is also a Co-Principal Investigator for the subject project and therefore familiar with the operations and goals of the program.

SwRI provided the resulting processed electronic pre-hospital data files for qualifying cases to USAISR along with associated SA EMS run-sheets and case-file forms with personal identifying information deleted, for use in the Advanced Capabilities for Combat Medics research program. SwRI also provided a summary of relevant case times to USAISR as derived from the subject data.

A primary area of investigation relative to the hypothesis proposed for the subject research included evaluation of the potential that collection of target pre-hospital patient data can begin earlier in qualifying trauma cases within a ground EMS first responder service than for helicopter ambulance services. Often, helicopter services are launched after first responders are on a scene to assess the need for air transport. Ground EMS services often treat, stabilize, and package patients for air transport while helicopters are enroute to a scene. Helicopter services also typically operate over much larger geographical areas than ground EMS systems.

Using data for qualifying SA EMS cases provided by SwRI, USAISR conducted an analysis of the time intervals between estimated time-of-injury and the onset of acquisition of patient physiological data (Initial Data Delay - IDD) for the 25 ground EMS cases versus a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 Trauma Centers by air services. Comparative analysis of the two data sets by SwRI and USAISR demonstrated that for these samples, the helicopter service experienced an almost 15 minutes longer Mean Initial Data Delay (MIDD) than the MIDD experienced by the ground EMS first responder system. Analysis of the variances between the two data sets showed a significant difference between the two groups ($p<0.05$). A summary of statistical values derived from analysis of the two data populations is presented in Table 2.

Table 2. Statistical Summary of Initial Data Delay Times for Air and Ground Services

	Ground EMS Service (n=25);(hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ=Gnd-Air (hr:min:sec)
Mean Initial Data Delay (MIDD)	00:23:15	00:37:59	00:14:44
Standard Deviation	00:07:25.6	00:19:34.8	00:12:09.2
Range	00:32:26	01:28:41	00:56:15
95% Confidence Interval	00:26:19	00:43:11	00:16:52
Upper bound 95% Confidence Interval	00:20:12	00:32:48	00:12:36
Lower Bound			

The operational significance of the shorter IDD experienced in the ground EMS system is that physiological data reflecting parametric measurements and trends for severely injured patients begins sooner after an injury. For these samples, the helicopter data began 63.4% (MIDD) later than the ground EMS system after the estimated time-of-injury. This data supports the hypothesis proposed for this research. The clinical significance of earlier post-injury onset of data capture

for code 3 trauma patients within the Advanced Capabilities for the Combat Medic program will continue to be investigated by USAISR and SwRI.

Phase 1 (initial award)
Subtask 3.d Final Report

The Final Report for Phase 1 was delivered on December 20, 2006.

PHASE 1 (modified)
TASK 4 To investigate and begin implementation of new SAFD EMS physiological monitor pre-hospital data collection interfaces and operations.

Phase 1 (modified)
Subtask 4.a Investigate new SAFD EMS monitor configuration and data extraction/processing tools.

SA EMS had been using a mix of physiological monitors in its operating fleet due to budget constraints, with about one-third of the fleet using the data-capable LifePak 12 monitor. SA EMS recently adopted a system-wide conversion to a new physiological monitor, and the conversion to the new monitor occurred after SwRI and SA EMS completed the planned pre-hospital electronic data collection operations for this project. The new monitor is a Philips HeartStart MRx, which appeared to be capable of storing and delivering patient data acquired during emergency response operations. While this change would require adjustments in order to continue CCCE data collection and research operations and improvements, the long-term benefits would include many expanded opportunities for CCCE data collection and research. SwRI requested and received approval for a six-month no-cost time extension for the subject project in order to react to the equipment change in project ambulances. The planned added work was reflected in an additional task (Task 4) added to the approved SOW.

SwRI met with SA EMS staff and the SA EMS Medical Director on numerous occasions to understand the protocols and standard operations that define the configuration and use of the new monitor for qualifying cases for this project. For routine code 3 adult trauma cases, the monitor is applied to the patient early in the response and typically after the patient is in the ambulance. Electrocardiograph (ECG) and End Tidal Carbon Dioxide ($ETCO_2$) parameters are acquired and are available on the screen of the monitor as scrolling waveforms, and this data is also captured in the monitor memory. Additionally, discrete values for Non-Invasive Blood Pressure (NIBP), Oxygen Saturation (SPO_2), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Heart Rate (HR), Pulse Rate (PR), Respiration Rate (RR), and Blood Pressure Pulse Rate (BPPR) are measured or derived by the instrument and made available to the operator and captured in the device memory. Events relative to a patient monitoring session, either prompted by operator commands or by monitoring alarm conditions, etc. are also captured in the device memory.

Commercially available software tools compatible with the MRx that have been identified by SwRI are designed to meet operational needs of EMS systems and provide case reporting capabilities, to include viewing of waveforms and noted measurements and events on a computer screen. The tools are also capable of providing electronic case summary reports to be included

in medical charts and for quality control and other medical records purposes. The case summary reporting is designed to comply with National EMS Information System (NEMSIS) standard reporting formats, as sponsored and adopted by the Centers for Disease Control (CDC), the National Highway Traffic and Safety Administration (NHTSA), and others.

The use of such products does not produce or preserve data content for this project. Much of the detail information, including digital sampled values of acquired waveforms, is discarded, changed, or otherwise corrupted in the processing that occurs once raw data from the monitor memory is imported and processed to produce viewable or storable report products for the targeted EMS and medical records purposes. Consultation with Philips Medical Systems engineering staff by SwRI reinforced that much needed information for this project acquired and stored within the monitor is discarded or changed during processing by the case review program products to produce the NEMSIS-compliant reports and summaries.

Phase 1 (modified)

Subtask 4.b Investigate new SAFD EMS monitor data collection interfaces and process compatible with ground EMS operations.

SwRI met with representatives from Philips Medical Systems and obtained user documentation for the Philips HeartStart MRx monitor. SwRI also accessed working models of the monitor at SA EMS to test and evaluate the monitor's data management capabilities and interfaces. SwRI participated in numerous meetings and discussions with engineering and development staff at Philips Medical Systems, supplier of the MRx, to better understand the data management capabilities provided by the monitor and plans for improvement.

Currently, to acquire data stored in the monitor, an operator must engage the controls and display of the monitor in a sequence of interactive operations to identify, select, and transfer data from the monitor memory to a small memory card. The operator must have prior knowledge of information about the case of interest, including which monitor was used and the date and time (as recorded by the clock within the monitor) of the incident. The operator must enter a data management mode on the monitor and navigate through several screens to select the appropriate case file. Once the file of interest is selected, the operator can cause the file to be transferred to a Compact Flash (CF) memory card that is plugged into a port provided on the monitor. The CF card can then be removed and the file can be moved to another computer using the CF card. The data in each case file at this point consists of a series of XML and binary files containing coordinated but distributed information about measurements and events recorded during use. The structure and format variables reflected in the raw data files is proprietary. The raw data files extracted from the monitor memory require significant interpretation and processing to arrive at the data content and format needed for the CCCE program.

The memory available in the monitor is finite. The system can store approximately fifty typical case files as generated in use by SA EMS. Fewer files will be stored if the files become large due to extended operations or using data-intensive modes of operation. While qualifying cases for this project use relatively simple monitor processing configurations, the monitor also provides 12-lead ECG and defibrillator functions for cardiac cases. Some operational modes used by SA EMS can generate very large stored data files. As for the LifePak 12 monitor, if data for a case of interest is not recovered soon after a qualifying case is active, the data stored in the

monitor may be lost. Continued use of the monitor by SA EMS results in additional cases stored in the monitor memory, and the "oldest" case files in the monitor memory are deleted as needed to accommodate new case file data.

Phase 1 (modified)
Subtask 4.c Develop and test proof-of-concept pre-hospital data collection and process capability based on new physiological monitor and Data Integration Software Development Kit tools.

SwRI worked with SA EMS to acquire reference case file data provided by the MRx monitor configured as used for qualifying cases for this project. Healthy volunteers (SA EMS paramedics) conducting monitor training sessions on each other produced the reference files, and SwRI accessed the monitor after the event to extract the reference data files.

With support from Philips Medical Systems engineering and research staff, SwRI researched and developed a capability to interpret and process the reference raw data files derived from the monitor memory to produce the data content and format needed for the CCCE program. The procedures developed by SwRI to process the raw monitor data is a proof-of-concept approach. Research and use of the procedures by SwRI indicated that data content needed for the CCCE program is available in the raw data files produced by the MRx monitor. The research and procedures also demonstrated that SwRI understands the basic structure and content of the monitor files sufficiently to interpret the data and produce the XML data files needed for import of case data into the CCCE project database. Future work was needed to improve, enhance, and further validate the SwRI-developed proof-of-concept data processing capabilities.

PHASE 2 (initial award)
TASK 1. Implement improved field data collection process.

mapped to

PHASE 2 (modified)
TASK 1. To Develop and Implement Incremental Collection and Process Improvements.

Phase 2 (initial award)
Subtask 1.b Develop semi-automated field data collection system.

mapped to

Phase 2 (modified)
Subtask 1.a Collaborate with SA EMS and vendors to facilitate Trauma Vitals data content in developing data management procedures.

SwRI conducted numerous meetings and discussions with Philips Medical Systems, supplier of the new Philips MRx monitor, to explore current and planned capabilities for data transfer provided by the monitor and processing of monitor data facilitated by Philips' related software development kit.

Initial investigations of the MRx monitor have revealed that the data management capabilities of the monitor are currently limited but are scheduled for upgrade during 2007. A similar situation exists with the monitor manufacturer's Software Developer's Kit (SDK) and compatible commercially available medical record products. There is currently little opportunity for collection of data by other than manual methods similar to the process used with the LifePak 12 monitor during the Phase 1 proof-of-concept data collection interval. Numerous manual operations are currently required to extract data for qualifying cases from the monitor memory after a qualifying transport is completed.

As the planned upgraded MRx monitor firmware becomes available in the future, however, SwRI will continue working with SA EMS and vendors of the monitor and reporting products to preserve data content needed for the CCCE program during future SA EMS medical records operations as reflected in the modified SOW for Phase 2.

SwRI also conducted numerous meetings with SA EMS to understand current data collection technical and logistics issues and opportunities in system operations. Logistical issues relative to acquiring and collecting patient monitor data for qualifying cases in a large metropolitan EMS system are formidable. Collection operations that require special operations by paramedics in the field are problematic. SwRI and SA EMS have examined procedural issues and the user interfaces and operations currently available within the MRx monitor in order to arrive at data acquisition and transfer concepts that can support practical manual field data collection operations.

Also, SA EMS has begun planning for the future to collect and store case summary reports from the MRx monitor for medical records for all patients. The planned National EMS Information System (NEMSIS) compliant case summary reports will not include some content needed for the CCCE program, but SwRI is working with SA EMS and the monitor manufacturer to preserve needed data content.

Phase 2 (initial award)
Subtask 1.b Develop semi-automated field data collection system.

mapped to

Phase 2 (modified)
Subtask 1.b Integrate and adapt evolving monitor and EMS data management in Trauma Vitals pre-hospital patient data collection.

SwRI developed data processing algorithms to be used in extracting and formatting patient case data provided by the MRx monitor currently in use by the SA EMS system. This work was based on SwRI's understanding of the content and format of relevant data within the case files produced by the MRx monitor as developed during Phase 1, Task 4 project work. The raw files containing relevant patient data are produced and stored within the monitor during patient care and are extracted from the monitor retrospectively for project data collection purposes. SwRI's algorithms organize the data into XML reports containing content and formatting usable by the

CCCE program. The algorithms also read and process embedded case timing information to facilitate case association and case timing analysis. The specially developed algorithms are also capable of organizing variable strings representing physiological waveform data into comma separated variable files, which facilitate the use of experimental signal processing and validation techniques.

SwRI investigated the results of numerous sample data conversions using sample data acquired by employing an MRx monitor on un-identified paramedic volunteers. The processing algorithm investigations were conducted interactively as a number of questions were answered through contact with the monitor manufacturer or by project research and investigations. A number of refinements to the structure and operation and operator interfaces were also incorporated during the development of the process algorithms. SwRI also conducted investigations and research to answer data- and format-related questions arising from the developing data process techniques and validate the algorithm output by comparison of selected output data against the output of commercially available case reporting software provided by the monitor manufacturer. It is anticipated that SwRI will soon begin processing data collected for multiple real trauma cases acquired in a dynamic, stressful, and sometimes chaotic environment during field care and transport of seriously injured patients. Further development and refinement of the data processing algorithms is anticipated as variability in procedural and case anatomy are encountered.

Phase 2 (initial award)
Subtask 1.b Collaborate with ISR on Trauma Vitals data research and data mining and visualization methods.

mapped to

Phase 2 (modified)
Subtask 1.c Support and collaborate with ISR on Trauma Vitals data research objectives and data mining and visualization methods.

SwRI conducted initial meetings with USAISR to begin to understand current and planned data research capabilities and approaches at USAIR within the CCCE project. SwRI presented a number of data mining, processing, and visualization concepts that have been derived from previous work. Continuing efforts to understand and plan complementary collaboration in data processing and visualization are ongoing at SwRI

PHASE 2 (initial award)
TASK 2. Continue/expand collection and research of EMS Trauma Vitals data.

mapped to

PHASE 2 (modified)
TASK 2. To Conduct First Data Acquisition Interval – Manual Data Collect Methods.

Phase 2 (initial award)
Subtask 1.b Develop semi-automated field data collection system.

mapped to

Phase 2 (modified)
Subtask 2.a Develop operational procedures; prepare, train, and coordinate with EMS.

SwRI has initiated renewal and/or modification of planned sub-awards and agreements to facilitate Phase 2 data collection and processing operations. This includes consulting agreements for off-time data collection operations by selected SA EMS paramedics and staff, consulting for case association and analysis by the Medical Director for SA EMS, and provisions for research nurse work at USAISR in collecting and processing in-hospital data for relevant qualifying cases for the CCCE program.

SwRI has coordinated and planned with SA EMS to establish procedures and processes for manually identifying candidate qualifying cases (code 3 adult trauma cases) and to acquire the raw MRx case data files and SA EMS runsheet data (without personal identifying information) for the identified cases. For the planned first (manual) Phase 2 interval of data collection, this process will involve physical interception of each ambulance that was involved in each of the qualifying cases and access to the physiological monitor that was in use. The raw data files for candidate cases are then manually selected and transferred from the monitor internal memory and stored on a portable memory card.

SwRI has configured a data acquisition laptop PC to be used in extracting and storing the collected raw MRx case data files from the memory cards. The case files are labeled with an encrypted alpha-numeric eight-character label at this point and are not readily associable with qualifying case information. In order to facilitate secure and private handling of this information and to minimize potential confusion and the potential for human error, SwRI developed a special data transfer algorithm that is deployed on the data acquisition laptop. The algorithm provides the capability to extract SA EMS unit number and case date and time information from the raw MRx data files and display this information to the user. Once this "case identifier" information is compared with the previously manually identified candidate qualifying case list, the algorithm provides a prompt to the operator to initiate automatic data transfer from the memory card to the laptop PC. The data is organized by time and date of the data transfer from the memory card to the laptop and the raw MRx case data files are stored within folders labeled with SA EMS unit number and case date and time. SwRI coordinated with consulting SA EMS staff and trained the field data collection personnel on the case identification and data extraction and transfer procedures.

PHASE 2 (initial award)
TASK 3. Investigate improved mobile remote ultrasound techniques

mapped to

PHASE 2 (modified)
TASK 5. To Investigate Improved Mobile Ultrasound Techniques.

Phase 2 (initial award)
Subtask 3.a Investigate improved video compression/wireless communications techniques.

mapped to

Phase 2 (modified)
Subtask 1.a Investigate improved video compression/wireless communications techniques.

SwRI conducted initial meetings with research and support staff from BAMC, Department of Cardiology, to discuss concepts for continuing research in improved transmission and remote interpretation of diagnostic ultrasound images and data between field locations and a hospital.

Key Research Accomplishments

- Pre-hospital physiological data and corresponding SA EMS run-sheets and case forms resulting from the Phase 1 data collection interval were processed and delivered to USAISR for use in the CCCE project.

- Comparative statistical analyses of data sets relevant to the aims of the subject project and resulting from ground and air data collection operations were conducted and the results reported. Results of the analysis support the hypothesis proposed in this research program (see Reportable Outcomes below).

- The planned renewal of five LifeLink project ambulances was completed, and the vehicles were returned to service.

- An independent raw-data recovery process and tool for the LifePak 12 physiological monitor were developed and tested.

- A special physiological data-extraction utility to process LifePak 12 monitor data into reports consistent with the content and format needs for the CCCE database program was developed, refined and tested.

- A new data-capable monitor (Philips MRx Heartstart) was adopted by SA EMS to replace the mix of LifePak monitors in the system, and MRx monitors were deployed throughout the entire fleet. The capabilities and configuration of the MRx monitor and commercially available data processing products relative to this project were researched and evaluated.

- MRx data collection interfaces and operational processes that may be consistent with routine SA EMS operations were explored, and opportunities and problems were defined.

- The content and structure of data files produced by the MRx monitor during patient care were researched, and a proof-of-concept capability to extract and process this data for use in the CCCE program was developed.

- Working relationships were established with the MRx monitor manufacturer to understand and influence evolving monitor data management upgrades and case-management software development kits. These upgrades will be reflected in near future operational upgrades in SA EMS operations. This work is focused on preserving the raw data content required for project research purposes.

- Working relationships were established with SA EMS staff that is working toward organizational pre-hospital data collection and storage for medical records purposes. This work is focused on preserving the raw data content required for project research purposes and improving the efficiency of collecting project data in the future.
- A project data acquisition laptop PC has been configured with special algorithms to facilitate extraction and organized storage of raw MRx case data files that have been transferred to portable memory cards within the MRx monitor device.

- Special data processing algorithms have been developed and tested for extracting and formatting patient case data and relevant monitor configuration and operations information provided by the MRx monitor currently in use by the SA EMS system. The raw files containing relevant patient physiological data are processed and organized into XML reports containing content and formatting usable by the CCCE program. The algorithms also read and process embedded case timing information to facilitate case association and case timing analysis.

- Special data processing algorithms have also been developed and tested for extracting and processing selected patient case data as provided by the MRx monitor to provide numerical strings of waveform sample data in common file formats usable for experimental digital signal processing and research operations.

- Procedures have been developed, and coordination and other preparations have been made to facilitate an initial field data collection interval of operations as planned for Phase 2. It is anticipated that the initial data collection operations will be accomplished during April 2007.

Reportable Outcomes

- Pre-hospital physiological data for 25 qualifying adult code 3 trauma cases cared for by the crews of a fleet of ten SA EMS ground ambulances and transported to three Level 1 trauma centers was acquired prior the subject reporting period. SA EMS run-sheets and case forms for these cases were acquired during the reporting period. The data has been processed to conform to the needs of the CCCE database program and delivered to USAISR to facilitate related research activities. The number of qualifying cases for which data was collected exceeded expectations significantly because the project team was able to involve twice the number of participating ambulances and additional participating hospitals in the data collection process than planned.

- USAISR conducted an analysis of the time intervals between estimated time-of-injury and the onset of acquisition of patient physiological data (Initial Data Delay - IDD) for the 25 qualifying ground SA EMS cases for which data was collected versus a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 trauma centers by air services. Comparative analysis of the two data sets by SwRI and USAISR demonstrated that the helicopter service experienced a Mean Initial Data Delay (MIDD) almost 15 minutes longer than the MIDD experienced by the ground EMS first responder system. The operational significance of the shorter IDD experienced in the ground EMS system is that physiological data reflecting parametric measurements and trends for severely injured patients begins sooner after an injury in the ground system. For these samples, the helicopter data collection began 63.4% (MIDD) later post-injury than in the ground EMS system. These results are interpreted to substantiate the hypothesis proposed for the subject project.

- Five operational ambulances have been equipped and tested to operate within the LifeLink network and have been returned to service within the SA EMS system.

- Manual (proof-of-concept) data collection and processing capabilities have been developed and tested for the new data-capable monitor that has been deployed system-wide within SA EMS, replacing a mix of older monitors.

- Initiatives have been established to coordinate project data needs with evolving hardware and software data management capabilities relative to the new MRx monitor. Similar initiatives have been established to coordinate project data needs with planning for implementation of a medical record system including routine patient physiological data reporting.

- Initial steps for developing practical and sustainable data collection and data processing capabilities to facilitate field data collection have been taken. Algorithms have been developed, tested, and deployed for extracting and handling raw data for qualifying cases as acquired in SA EMS operations and for processing the raw data to produce data content and formats needed by the CCCE program. These initial tools will likely need refinement as experience is gained during actual data collection operations and as the data management capabilities and procedures are upgraded.

- SwRI has developed a new initiative to support and expand the data collection and research operations that are part of the CCCE program. The Parameter-based Remote Objective Pre-Hospital Emergency Triage (PROPHET) program has achieved first-year funding support, and future support is anticipated.

Conclusions

Significant amounts of high quality, but difficult to acquire, data are needed for the CCCE project. The nature of the research program suggests that obtaining data for trauma patients during the prehospital phase is advantageous to development of future triage, treatment, and decision support systems. Collection of data and trending parameters beginning soon after an injury occurs may yield particularly relevant and usable information.

The development of a system to collect data using a fleet of ground EMS ambulances operating in a large municipality that routinely transport trauma patients to both military and civilian trauma centers is the focus of this project. Further, the existence of a widely distributed mobile broadband digital communications link between ambulances in the field and the trauma centers (the LifeLink project) could help facilitate more transparent and easily managed data collection in the emergency patient pre-hospital care environment. During the reporting period, SwRI obtained access to five relatively new SA EMS ambulances and completed the planned upgrade of these units as needed for operation within the LifeLink system.

Also, during the reporting period, SwRI operated with SA EMS to conduct the planned one-month proof-of-concept pre-hospital data collection interval during Phase 1 of the project. A larger volume of the target data was collected than planned during the time available for these operations. This was due to recognition of un-planned opportunities for the project partners to make adjustments during the data collection period to increase the number of participating ground ambulances and hospitals to add to the number of qualifying cases encountered. Analysis of the project data and comparison of the analysis results to a similar data sample collected within operations of a helicopter EMS service shows that data collection activities within primary patient care protocols began significantly earlier in the injury events within the ground-based system than for comparative cases transported by helicopter services.

Subsequent to the completion of the planned proof-of-concept data collection operations, SA EMS embarked on a system-wide change to a new, more capable monitor to be used in patient care. This change resulted in more than three times as many operating ambulances that could support data collection available to the project. The change also required the project team to learn about the capabilities and functions of the new monitor and to adapt to the different data characteristics and formats produced by it in order to prepare for continued data collection operations. SwRI worked with SA EMS and the manufacturer of the new monitor to understand the data management capabilities of the new device. SwRI acquired relevant reference volunteer-patient data from the new monitor, and with the support of the manufacturer, developed a proof-of-concept capability to extract and process the raw monitor data to meet the needs of the CCCE project.

Phase 2 of the subject project was initiated during the reporting period, and early work began in researching and learning to provide for practical data collection operations and data processing capabilities for data collected using the new SA EMS monitor. Existing data management capabilities provided by the new monitor require significant manual operations to acquire the needed data for qualifying cases. Upgraded monitor data management capabilities are anticipated in the near future. Also, the SA EMS system is moving toward routine collection and storage of monitor data for all patients for medical records purposes. Therefore, SwRI proposed a re-direction of the planned Phase 2 project work in order to accelerate data collection operations and to include multiple expanded data collection intervals, thereby significantly increasing the amount of data collected during Phase 2. This work will be coordinated with the planned upgrades of monitor data management capabilities and the evolving routine data collection processes planned by SA EMS. An initial "manual" data collection interval using existing monitor data management capabilities was also planned in order to immediately begin acquiring needed data.

The planned upgrades for the monitor data management capabilities can facilitate improved and more efficient pre-hospital patient data collection operations. The patient data to be collected and processed by SA EMS for medical records, using a commercially available EMS information system product that is currently in development, is not sufficient to meet the requirements of the CCCE program. Therefore, SwRI is working with SA EMS, the monitor manufacturer, and the EMS information system vendor to preserve raw monitor data in the planned SA EMS routine data collection and medical records processing in order to facilitate future independent data research operations as needed for this program. SwRI has also begun planned work in Phase 2 to support ISR in data mining and visualization techniques and in furthering previous work in investigation of improved methods and results for transmission and interpretation of selected diagnostic ultrasound images as sent to a hospital from remote mobile field platforms.

Finally, SwRI has developed an initiative based on the subject initial project to include future automation, expansion, and extension of the data collection and CCCE research. The PROPHET initiative has achieved initial funding support, and it is anticipated that this support will be continued and expanded in the future. The PROPHET program and its relationship to emergency patient care was showcased during a live emergency drill within a major convention. Future plans for the PROPHET program include refinement, automation, extension, and expansion of the data collection efforts. Additional research components will be added to further analyze collected data to help identify meaningful predictive trends and algorithms and to expand data gathering and research work to include additional potential field triage advances. It is anticipated that this work will ultimately lead to deployable prototype equipment, field and clinical trials, and development/distribution of the technologies to military as well as civilian casualty care organizations.